REMARKS

Claims 1-16 and 18 are pending. Claim 17 has been deleted without disclaimer or prejudice.

Claims 1-12 and 18 were withdrawn from consideration as being drawn to a nonelected group or species. Only claims 13-17 were examined. However, the withdrawal and the non-consideration of SEQ ID NO.'s 7, 9 and 18 is improper as discussed in section 1 below and examination of SEQ ID NO.'s 7, 9 and 18 is again requested. The claims have not been otherwise amended but amendment to limit them to SEQ ID NO.'s 7, 9 and 18 is proffered. This proffer is not related to any substantial question of patentability and is only advanced in view of the outstanding restriction. Applicants do not disclaim any portion of the remaining SEQ ID NO.'s 1-6, 8, 10-17 and 19-28.

The specification has been amended to recite textual description for the variant amino acids at position 6 in SEQ ID NO.7 and the MISC_FEATURE amino acid modifications disclosed in the "Sequence Listing". For example, the amended specification at page 5 provides that the amino acid at position 6 for SEQ ID NO.7 can be optionally Val or Leu or Ile or Gly or Ala and provides a listing of the various MISC_FEATURE and residue position. Conforming amendments have been made for SEQ ID NO.'s 9 and 18 at pages 21 and 24. Support for each of the amendments can be found in the corresponding SEQ ID NO. in the "Sequence Listing", which is considered part of the specification. The specification has further been amended to

make reference to accompanying SEQ ID NO. designators at pages 10 and 20-28. No new matter within the meaning of § 132 has been added by the amendments.

An affidavit or declaration is submitted under 37 C.F.R. § 1.132 establishing that the contents of the cited reference, *Vaccine 19:4750-4759,* ("Zimmerman *et al.*") describes Applicant, Dr. Zimmerman's, own work.

1. **Refusal to Consider Applicants' Elections is Improper**

The Office Action refused the election of SEQ ID NO.'s 7, 9 and 18 because unity of invention applies to a species election as well as to groups of inventions. Citing MPEP 1850 and Annex B of the Administrative Instructions Under The PCT.

Applicants do not dispute this assertion but rather point out that SEQ ID NO.'s 7, 9 and 18 share a technical relationship involving the same or corresponding "special technical feature".

PCT Rule 13.2 states that where a group of inventions is claimed in the same international application, the requirement of unity of invention shall be fulfilled if there is the same or corresponding "special technical features" where the expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In this case, SEQ ID NO. 7 is:

DGQEEXAGVVSTGLIGGG

SEQ ID NO. 9 is:

DGQEEXAGVVSTGLIGGG

SEQ ID NO. 18 is:

DGQEEKAGVVSTGLI

Clearly, SEQ ID NO.'s 7, 9 and 18 share a technical relationship. In view of this, the refusal to examine SEQ ID NO.'s 7, 9 and 18 is improper and it is requested that the sequences be examined together.

The withdrawal of claims 1-12 and 18 from consideration is similarly improper because the original restriction was for two (2) Groups: Group I being drawn to claims 1-4, 6-10 and 12-17 (elected), and Group II drawn to claims 5, 11 and 18. Although a species election was made for infection by virus or phage, the restriction arbitrarily divided the claimed conditions without any regard for the manner in which they were claimed or taught in the specification.

Contrary to the Office Action's assertion, PCT Rule 13.2 does not apply to the species election but only to election of the invention. In particular, Annex B of the PCT Administrative Instructions clearly states that unity of invention determinations apply to groups of inventions. In fact, the only reference to "species" in Annex B, sections (c)(i) and (ii), relates to independent and dependent claims, which has no bearing on the species/invention dichotomy. Hence, the originally elected claims 1-4, 6-10 and 12-17 must be examined in conformance with Unity of Invention guidelines.

2. **Objections**

The Office Action objected to sequence recitations listed in the specification without an accompanying SEQ ID designator at pages 10 and 20-28. The Office Action alleged that the specification is incorrect in using SEQ ID NO. 7 for the derG sequence presented on page 5, and in using nonspecific SEQ ID NO.'s 9 and 18 to refer to the specific sequences presented on pages 21 and 24. An amendment to the Sequence Listing adding SEQ ID NO. 29 corresponding to "AcVAKEamide" on paragraph [0078] on page 28 of the specification is proffered.

The specification has been amended to include textual description for the variants Xaa's as supported by the specification and to use specific SEQ ID NO.'s 9 and 18 and accompanying description to refer to the sequences presented on pages 10 and 20-28. Each of the amendments are directly supported by the MISC_FEATURE amino acid modifications disclosed in the Sequence Listing.

3. **Rejection of Claims 13-17 under 35 U.S.C. § 112, ¶ 2 (indefiniteness)**

The Office Action rejected claims 13-17 because the specification stated that SEQ ID NO.7 is the same as derG, with the sequence Asp Gly Gln Glu Glu Lys Ala Gly Val Val Ser Thr Gly Leu Ile whereas the "Sequence Listing" has a different structure for SEQ ID NO.7, (Asp or cyclohexylalanine or D- alanine) Gly Gln Glu Glu (Val or Leu or Ile or Gly or Ala) Ala Gly Val Val Ser Thr Gly Leu Ile where the sequences are allegedly

incompatible at residue 6.

The assertion that SEQ ID NO.7 at position 1 can be "Asp or cyclohexylalanine or D- alanine" is incorrect. The amino acid is Asp where the MISC_FEATURE at position 1 can optionally be cyclohexylalanine or D- alanine. The specification has been amended to include textual description for the variant amino acid at position 6 as supported by the "Sequence Listing". For example, the specification provides that the amino acid at position 6 for SEQ ID NO.7 can be optionally Val or Leu or Ile or Gly or Ala. Conforming amendments have also been made in the appropriate locations in the specification for SEQ ID NO.'s 9 and 18.

The Office Action rejected claim 17 as being indefinite for reciting "compositions suitable for military applications". Claim 17 has been deleted.

4. **Rejection of Claims 13-17 under 35 U.S.C. § 112, ¶ 1 (enablement)**

The Office Action rejected claims 13-17 because the specification, while being enabling for the use of derG or SEQ ID NO. 7, 9, and 18 as an adjuvant and for a method of ameliorating zosteriform herpes virus by administering derG before infection, allegedly fails to provide enablement for the claimed method for treating infections and conditions. The Office Action also alleged that the teaching of replacing Asn to Asp alters the biological activity of peptide G in an "unpredictable manner".

The rejection is traversed because one of ordinary skill in the art would know how

to make and use the claimed methods without undue experimentation. The breadth of the claims is sufficiently enabled by the teaching of a single example of ameliorating zosteriform herpes virus by administering derG before infection. As noted by the Federal Circuit, so long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. See In re Fisher, 166 USPQ 18, 24 (C.C.P.A. 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. See Spectra-Physics, Inc. v. Coherent, Inc., 3 USPQ2d 1737, 1743 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987).

For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph. The Applicant need not demonstrate that the invention is completely safe. See 2164.01(c); See also MPEP § 2107.01 and § 2107.03.

In the present case, it is well known that phages (or bacteriophages) are viruses that infect bacterium, *i.e.* microorganisms not having a nucleus as opposed to viruses that infect cells having a nucleus. Clearly, the claimed method of treating infections by

viruses or phages is within the scope of the working example such that one skilled in the art would be sufficiently apprised of how to practice the methods with the claimed compounds. See AK Steel Corp. v. Sollac, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003); In re Moore, 169 USPQ 236, 239 (CCPA 1971). The Applicants do not need to provide data and examples for each and every possible method of treating infections by viruses or phages as suggested, particularly in view of the immunological effect of the claimed compounds.

The variant at position 6 for SEQ ID NO. 7 is disclosed in the specification at page 33, paragraph [61] as being optionally Val or Leu or Ile or Gly or Ala and being non-polar. Each is a conserved substitution of a similar type of amino acids. See Specification at Table 1. This non-polar grouping is well known in the art and does not alter biological activity in an "unpredictable manner" as suggested by the Office Action.

Moreover, the various N terminal changes such as acetyl, propionyl, BrAc, ClAc, substitution of D amino acids, cyclohexylalanine-, D-amino acids, and internal changes or substitutions such as use of GABA or 5-aminopentanoic acid, are intended to increase stability *in vivo* by reducing the sensitivity of the modified peptide to endogenous proteinases or to amino-peptidases, which in some cases act to cleave at the amino acid terminus or those that cleave between normal peptide bonds. It is well known that Asn is prone to deamidation, cyclization and reformation as isoaspartic or aspartic in a random fashion.

Since the amount of guidance or direction needed to enable the invention is

inversely related to the amount of knowledge in the state of the art as well as the predictability in the art, it is clear that information in the captioned application, as originally filed, teaches exactly how to make or use the invention. See In re Fisher, 166 USPQ 18, 24 (C.C.P.A. 1970). In view of this and above, the claimed and elected species of the methods are clearly enabled by the specification, and the rejection is requested withdrawn.

5. **Rejection of Claims 13-15 and 17 under 35 U.S.C. § 103(a) obviousness**

The Office Action rejected the claims over, *Vaccine 19:4750-4759,* ("Zimmerman *et al.*").

The rejection is traversed because Zimmerman *et al.* is not prior art against the captioned application. Zimmerman *et al.* was published less than one year prior to the earliest effective filing date of January 23, 2002, of the captioned application and therefore cannot be a statutory bar under § 102(b). For purposes of § 102(a), the claimed invention is solely attributed to Dr. Daniel Zimmerman, the first named inventor and first listed author of the cited reference. In support thereof, Applicants submit an affidavit under 37 CFR § 1.132 establishing that the reference describes Dr. Zimmerman's own work. *In re Katz*, 215 U.S.P.Q. 14 (CCPA 1982).

Insofar as each and every claimed limitation has not been taught or suggested, the *prima facie* case of obviousness has not been established and the rejection is

requested withdrawn.

6. **Double Patenting Rejections**

(a) Application No. 11/696,124

The Office Action provisionally rejected claims 13-17 on the ground of nonstatutory obviousness-type double patenting over claims 1-5 of copending Application No. 11/696,124 ("the '124 application").

However, claims 1-5 of the '124 application generally relate to methods for treating Avian Flu using SEQ ID NO. 97 as an adjuvant in conjunction with a vaccine. Since the pending claims of the captioned application do not recite "an adjuvant in conjunction with a vaccine", there is no overlap and hence any double patenting.

(b) U.S. Patent No. 6,572,860

The Office Action rejected claims 13-15 and 17 on the ground of nonstatutory obviousness type double patenting over claim 6 of U.S. Patent No. 6,572,860 in view of WO 01/89286.

The rejection is improper because two references have been cited. Only one reference can be cited against the captioned application in a double patenting rejection. Moreover, claim 6 of the cited patent recites a method for the treatment of herpes simplex virus using a conjugated polypeptide according to claim 1, which is recited as

being "an immunogenic conjugated polypeptide effective as immunogen in a vaccine for treatment or prevention of infection by herpes simplex virus, said polypeptide represented by the formula P_1-x-P_2 or P_2-x-P_1 where P_1 represents a herpes simplex virus specific antigenic peptide from a protein of herpes simplex virus type 1 or type 2, . . .". Clearly, the claimed methods do not recite the same variants and hence there is no double patenting.

(c) U.S. Patent No. 6,951,647

The Office Action rejected claims 13-15 and 17 on the ground of nonstatutory obviousness type double patenting over claims 7-9 of U.S. Patent No. 6,951,647.

The rejection is improper because the pending claims relate to methods of treating diseases and conditions, whereas claims 7-9 of the patent recites a method of eliciting a cellular immune response.

CONCLUSION

In light of the foregoing, the application is now in condition for allowance. It is therefore respectfully requested that the rejection(s) be withdrawn and the application passed to issue.

Respectfully submitted,

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